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August 7, 2009

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**Re: Ellen Sigmund Costoso and Jack Costoso v. Amgen Inc., et al.,
09-3337 (KAM)**

Dear Judge Matsumoto:

Our firm represents defendants Amgen Inc. and Immunex Corporation (collectively, "Amgen") in the above-referenced matter. Together with co-counsel at Orrick, Herrington & Sutcliffe LLP, who represent co-defendants Wyeth and Wyeth Pharmaceuticals Inc. (collectively "Wyeth"), we write to request a pre-motion conference, in accordance with Your Honor's rules, as Amgen and Wyeth wish to move to dismiss the Complaint pursuant to Rules 8, 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure.

This is a product liability action in which Ellen Sigmund Costoso and Jack Costoso ("Plaintiffs") allege that Ellen Sigmund Costoso ("Plaintiff Costoso") was injured as a result of her use of Enbrel®, a biological product that has been approved by the United States Food and Drug Administration ("FDA") since 1998 for the treatment of various autoimmune diseases. In their Complaint, Plaintiffs attempt to plead eight causes of action: strict products liability, negligence, breach of express warranty, breach of implied warranty, fraudulent misrepresentation, breach of duty to warn, loss of consortium and punitive damages. Each of these claims, however, fails to satisfy the heightened pleading standard articulated recently by the Supreme Court in *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) because the Complaint is comprised of little more than a recitation of the legal elements of the pleaded causes of action with conclusory factual allegations. Such pleading is no longer sufficient.

As an initial matter, Plaintiffs have not sufficiently alleged the threshold elements of their product liability claims. See *Sita v. Danek Medical, Inc.*, 43 F. Supp. 2d 245, 252 (E.D.N.Y. 1999) (explaining that defect and injury are required to sustain claims for strict products liability, breach of warranty and negligence). Under New York law, a product may be defective because of a mistake in manufacturing, an improper design, or a failure to provide adequate warnings. *Id.* Plaintiffs' claims appear to stem from allegedly inadequate warnings.¹ This conclusion, however,

¹ Although the Plaintiffs' negligence claim consists of a boilerplate list of conclusory assertions, including that Enbrel® was negligently designed and manufactured, there are no well-pleaded factual allegations to support these claims. There is no mention in the Complaint of any mistake in manufacturing Enbrel®, and there is no allegation that the risks associated with Enbrel® outweighed its utility, a required element for a defective design claim. See *Sita*, 43 F. Supp. 2d at 255.

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is speculative because the Complaint does not set forth any facts to support this allegation, such as how the extensive warnings that accompany Enbrel® were in any way deficient. Such guesswork is inconsistent with the plausibility standard articulated in *Twombly* and *Iqbal*.

Nor does the Complaint even attempt to link the alleged inadequacy of the warning to Plaintiff Costoso's alleged injuries. In fact, the alleged injuries are never specified in the Complaint. Rather, they are simply characterized repeatedly as "severe, serious and permanent." (Complaint ¶¶ 8, 24.) Again, the lack of a specified injury warrants dismissal of the Complaint.

Similarly, Plaintiffs' fraudulent misrepresentation claim is deficient under Rule 12(b)(6) because Plaintiffs have not plausibly alleged any facts whatsoever to demonstrate that there was a representation of a material existing fact, falsity, scienter, reliance, and injury. *Albert Apt. Corp. v. Corbo Co.*, 582 N.Y.S.2d 409, 500 (1st Dep't 1992). Perhaps they have not done so because the facts do not permit such allegations. Enbrel®'s package insert clearly and comprehensively disclosed the potential risks of prescribing Enbrel®, including the potential risk of serious infection,² which appears to be Plaintiffs' focus (*see* Complaint ¶¶ 12, 14, 21), although, as noted, the Complaint does not identify specifically the alleged injury. This pleading style is no longer acceptable.

Plaintiffs' fraudulent misrepresentation claim should further be dismissed under Rule 9(b), which requires a party to state with particularity the circumstances constituting fraud. A complaint alleging fraud must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Wood v. Applied Research Associates, Inc.*, 2009 WL 2143829, at *2 (2d Cir. July 16, 2009) (quoting *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1128 (2d Cir. 1994)). This the Complaint does not do.

Plaintiffs' separate claim for punitive damages should also be dismissed because New York does not recognize a separate cause of action for punitive damages. *See Randi A.J. v. Long Island Surgi-Center*, 842 N.Y.S.2d 558, 564 (2nd Dep't 2007). And, Plaintiffs have not – and, indeed, cannot – identify any facts to support for such damages under any other claim. Under New York law, in order to recover punitive damages, a plaintiff must prove "exceptional misconduct," such as when the wrongdoer has acted "maliciously, wantonly, or with a recklessness that betokens an improper motive or vindictiveness." *Sharapata v. Town of Islip*, 56 N.Y.2d 332, 335 (1982) (citation omitted).

Even if the Court were to find that Plaintiffs have alleged sufficient non-conclusory factual allegations, which they have not, the Complaint must still be dismissed under *Iqbal* because Plaintiffs' claims do not "plausibly give rise to an entitlement to relief." *Iqbal*, 129 S. Ct. at 1950

² Plaintiffs' allegations that Enbrel® was not accompanied by proper warnings effectively incorporate the package insert as well as the description of Enbrel® in the PDR as an "integral" part of Plaintiffs' claims, and thus may be considered by the Court when assessing this motion to dismiss. *Chambers v. Time Warner, Inc.* 282 F.3d 147, 153 (2d Cir. 2002) (citation omitted). A copy of the package insert is attached as Exhibit A. The warning regarding the potential risk of infection is repeated throughout the insert. *See, e.g.*, Package Insert at 19, 24, and 29 (Ex. A).

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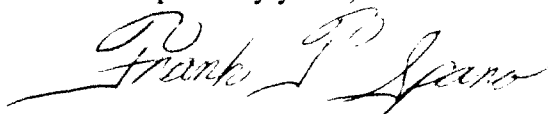
(explaining that dismissal is warranted “where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct.”). The warnings that accompanied Enbrel® provide a complete defense to Plaintiffs’ failure to warn and related claims because, under the learned intermediary doctrine, a drug’s warning “may be held adequate as a matter of law if it provides specific detailed information on the risks of the drug.” *Martin v. Hacker*, 83 N.Y.2d 1, 10 (1993). Warnings are intended for the physician, not the patient, who acts as an “informed intermediary.” *Id.* at 9. Because Enbrel® warns clearly and comprehensively of the exact injury alleged in this case – presumably, infection – the warnings are adequate as a matter of law. *See* Package Insert at 19, 24, 29 (Ex. A).³ The failure to warn claim should thus be dismissed. The claims for strict liability, negligence, misrepresentation, and breach of warranty should also be dismissed because a prescription drug accompanied by a proper warning is neither defective nor unreasonably dangerous. *See Sita*, 43 F. Supp. 2d at 259 (barring failure to warn claims under strict liability and negligence); *Browning v. Wyeth, Inc.*, 831 N.Y.S.2d 804, 804 (4th Dep’t 2007) (barring claim for misrepresentation); *Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95, 96-97 (4th Dep’t 1979), *aff’d* 52 N.Y.2d 768 (1980) (barring claims for breach of warranties).

This case was removed to this Court on August 3, 2009. Pursuant to Rule 81(c) of the Federal Rules of Civil Procedure, Amgen’s and Wyeth’s deadline for filing the motion to dismiss is August 10, 2009. By this letter, we request a pre-motion conference at which Amgen and Wyeth will seek the Court’s permission to file the motion to dismiss outlined in this letter. We also understand that pursuant to Your Honor’s rules, the filing of this letter serves as a timely response to the Complaint by Amgen and Wyeth.

Amgen and Wyeth propose the following briefing schedule for the motion to dismiss: Moving papers to be served fifteen (15) days after the pre-motion conference; opposing papers to be served forty-five (45) days after the pre-motion conference; and reply papers to be served sixty (60) days after the pre-motion conference.

Should Your Honor have any questions, I would be happy to respond. Thank you for your time and consideration.

Respectfully yours,



Frank T. Spano

³ The Warnings state, in part: “**INFECTIONS. IN POST-MARKETING REPORTS, SERIOUS INFECTIONS AND SEPSIS, INCLUDING FATALITIES, HAVE BEEN REPORTED WITH THE USE OF ENBRELO®.**” *See* Package Insert at 19 (Ex. A).

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VIA ELECTRONIC FILING

The Honorable Kiyo A. Matsumoto

United States District Judge

United States District Court

Eastern District of New York

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